



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,941	02/21/2006	Michael Horstmann	RO4150US (#90568)	7611
28672 7590 01/05/2011 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 01/05/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/568,941

Applicant(s)

HORSTMANN ET AL.

Examiner

MELISSA S. MERCIER

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,12-23,25,26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) 2-4,6-10,14-23,25 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,12-13,26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claims 1-4, 6-10, 12-23, 25-26, and 28 remain pending in this application. Claims 2-4, 6-10, 14-23, 25, and 28 remain withdrawn as reading on non-elected groups and species. Therefore, claims 1, 12-13, and 26 are under prosecution in this application.

### ***Withdrawn Rejections***

#### ***Claim Objections***

The objection of claim 5 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim has been withdrawn in view of Applicants cancellation of the claim.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1, 12, and 26 under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178) has been withdrawn after further consideration of the teachings of Bloom with regard to the combination of the components and the cancellation of orphenadrine from the claim.

The rejection of claims 13, 24, and 27 under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US Patent 5,614,178) in view of Andriola et al. (US Patent 4,666,441) has been withdrawn for the same reasons as discussed above.

***Newly Applied Rejections***

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klose et al (US 2004/0013620).

Klose discloses transdermal drug delivery systems comprising a therapeutically effective amount of an anti-Parkinson agent (abstract). Suitable anti-Parkinson's agents include levodopa and bornaprine (claims 8 and 11).

Klose does not exemplify the combination of the two active agents, however, It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected two components from a finite grouping of active agents which are useful for the same purpose to form a combination of active agents which is also useful for the same purpose. It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since the reference teaches that

both levodopa and bornaprine are effective agents in the treatment of Parkinson's disease, it would have been obvious to combine them with the expectation that such a combination would be effective in the treatment of Parkinson's disease. Thus, combining them flows logically from their having been individually taught in prior art.

Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrara et al. (US 2007/0225379).

Carrara discloses transdermal compositions which can be incorporated into patch devices. (paragraph 0031). The compositions include components which have an effect on the central nervous system, such as drugs to treat Parkinson's Disease (paragraph 0067). Examples of anti-Parkinson drugs disclosed include levodopa and bornaprine within a finite grouping of active agents. Mixtures of the disclosed agent are also disclosed as suitable for use (paragraph 0068).

Carrara does not exemplify the combination of the two active agents, however, It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected two components from a finite grouping of active agents which are useful for the same purpose to form a combination of active agents which is also useful for the same purpose. It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960).

Art Unit: 1615

As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since the reference teaches that both levodopa and bornaprine are effective agents in the treatment of Parkinson's disease, it would have been obvious to combine them with the expectation that such a combination would be effective in the treatment of Parkinson's disease. Thus, combining them flows logically from their having been individually taught in prior art.

Claims 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrara et al. (US 2007/0225379) in view of Andriola et al. (US Patent 4,666,441).

The teachings of Carrara are discussed above and applied in the same manner.

Carrara does not disclose the orientation of the transdermal device.

Andriola et al. disclose a multi-compartmentalized transdermal patch.

It would have been obvious to one of ordinary skill in the art at the invention was made to have utilized the patch of Andriola because it is disclosed that the advantages of the patch allows one to flexibly utilize drug formulations giving greater range of release rates and more precisely control drug delivery to the skin by utilizing different drug concentrations, different vehicles, different additives such as flux enhancers, and different materials having different drug transference rates (column 3, lines 57-68).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1615

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/Robert A. Wax/  
Supervisory Patent Examiner  
Art Unit 1615